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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,952	01/17/2002	Patricia S. Walker	D-2933CIP	2757
33197	7590	05/28/2004	EXAMINER	
STOUT, UXA, BUYAN & MULLINS LLP 4 VENTURE, SUITE 300 IRVINE, CA 92618			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,952

Applicant(s)

WALKER, PATRICIA S.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 7, 9, 10, 12 and 36-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 9, 10, 12 and 36-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-4, 6, 7, 9, 10, 12 and 36-44 are pending.

Applicant's amendment filed March 15, 2004 is acknowledged, and applicants' response has been fully considered. Claims 1-4, 6, 7, 9, 10, 12 have been amended, claims 5, 8, 11 and 13-35 have been cancelled, and new claims 36-44 have been added. Therefore, claims 1-4, 6, 7, 9, 10, 12 and 36-44 are examined.

Objection Withdrawn

Claim Objections

2. The previous objection of claims 1, 5, 10 and 11 is withdrawn in view of applicant's amendment to the claim, applicant's cancellation of the claim, and applicant's response at page 6 in the amendment filed March 15, 2004.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 1-12, under 35 U.S.C.112, first paragraph, is withdrawn in view of applicant's amendment to the claim, applicant's cancellation of the claim, and applicant's response at pages 6-7 in the amendment filed March 15, 2004.
4. The previous rejection of claims 1-12, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicant's amendment to the claim, applicant's cancellation of the claim, and applicant's response at page 7 in the amendment filed March 15, 2004.

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Claim Rejections - 35 USC § 103

5. The previous rejection of claims 5, 8 and 11, under 35 U.S.C. 103(a) as being unpatentable over Borodic (U. S. Patent 5,183,462) taken with Vadoud-Seyedi *et al.* (Dermatology 201, 179), is withdrawn in view of applicant's cancellation of the claim in the amendment filed March 15, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because of the use of the term "preferably solid or metallic material". The term "preferably solid or metallic material" renders the claim indefinite, it is unclear what other materials of the carrier are used for comparison as to "preferably solid or metallic material".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 1, 2, 6, 7, 9, 10, 12, 36, 37 and 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borodic (U. S. Patent 5,183,462) taken with Vadoud-Seyedi *et al.* (Dermatology 201, 179 (September 2000)).

Borodic discloses the injection of an appropriate dose of a botulinum toxin such as pharmaceutical grade botulinum toxin type A to interrupt nerve impulse transmission across the neuromuscular junction (column 4, lines 50-58; claims 7 and 41) and to attenuate tone of muscles about the eyes and forehead can remove wrinkles and brow furrows (column 3, line 67-column 4, line 6; column 9, lines 42-66; claims 1, 9, 10, 12, 36 and 42-44). However, Borodic does not disclose the use of a needleless syringe. Vadoud-Seyedi *et al.* disclose mouse botulinum toxin A in NaCl solution is injected into patients with plantar hyperhidrosis with a Dermojet (a needleless injection system; the whole document; claims 2, 6, 37 and 40). At the time of invention was made, it would have been obvious that one of ordinary skill in the art has been motivated to combine the two references to treat wrinkles and brow furrows by administering botulinum toxin A as taught by Borodic with a Dermojet as taught by Vadoud-Seyedi *et al.* because Vadoud-Seyedi *et al.* indicates the pain injection with a Dermojet is acceptable, and there were neither paresthesias nor other side effects, thus the injection of botulinum toxin with a Dermojet is an effective and comfortable technique (page 179, third and last paragraph). Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

8. Claims 3, 4, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borodic in view Vadoud-Seyedi *et al.* as applied to claims 1, 2, 6, 7, 9, 10, 12, 36, 37 and 40-44 above, further in view of McCabe *et al.* (U. S. Patent 5,525,510).

Borodic discloses the injection of an appropriate dose of a botulinum toxin such as pharmaceutical grade botulinum toxin type A to interrupt nerve impulse transmission across the neuromuscular junction (column 4, lines 50-58; claims 7 and 41) and to attenuate tone of muscles about the eyes and forehead can remove wrinkles and brow furrows (column 3, line 67-column 4, line 6; column 9, lines 42-66; claims 1, 9, 10, 12, 36 and 42-44); and Vadoud-Seyedi *et al.* disclose mouse botulinum toxin A in NaCl solution is injected into patients with plantar hyperhidrosis with a Dermojet (claims 2, 6, 37 and 40). However, Borodic and Vadoud-Seyedi *et al.* do not disclose the use of a botulinum toxin coated onto the carrier. McCabe *et al.* teach the biological material such as DNA, RNA, proteins or peptides is coated onto the carrier particles such as small gold beads or spheres (column 6, lines 22-35; claims 3, 4, 38 and 39). At the time of invention was made, it would have been obvious that one of ordinary skill in the art to combine the three references to treat wrinkles and brow furrows using the method taught by Borodic and Vadoud-Seyedi *et al.* with botulinum toxin A coated onto the gold sphere taught by McCabe *et al.* because the treatment with neurotoxin coated onto the gold particle would be safer since the high density carrier with small particle size would readily enter living cells without injuring the cells. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

In response, applicant indicates Vadoud-Seyedi *et al.* disclose needless injection of a botulinum toxin into the sole of a pateint's foot to treat plantar hyperhydrosis, the soles of the feet are targeted because of the deeper location of the plantar nerves (last paragraph), however, the needleless injection of botulinum toxin is not recommended for body regions containing superficial nerves or vessels such as the palms of a patient's hand; Boridic discloses

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administration of a botulinum toxin by injection using a syringe with a needle; wrinkles and brow furrows are relatively superficial cosmetic features formed by projections from muscles that attached into dermis, and the blood vessels and nerves in such body regions are superficially located, thus Vadoud-Seyedi *et al.* teach away from using a needleless injection of botulinum toxin into body regions having superficial nerves and vessels. Therefore, a person of ordinary skill in the art would not be motivated to treat wrinkles and brow furrows with a botulinum toxin by using a needleless syringe; claims 3 and 4 are similarly unobvious from and patentable over the combination of Borodic in view Vadoud-Seyedi *et al.* and further in view of McCabe *et al.*; and each of the present dependent claims is separately patentable over the prior art because none of the prior art disclose, teach or suggest the additional features recited in the claims. The response has been considered, however, the argument is not found persuasive because Vadoud-Seyedi *et al.* only indicate it is likely the injection with a Dermojet is safer and more appropriate for plantar than for palmer hyperhidrosis because of the deeper location of the plantar nerves and superficial palmar nerves or vessels, and the reference does not indicate the injection with a Dermojet is not proper for injection to other regions of body having superficial nerves or vessels. Since applicants indicate wrinkles and brow furrows are relatively superficial cosmetic features without scientific data presented, it is not clear how much similarity the superficial features of the blood vessels and nerves in the facial region has as compared to those in the palm. Moreover, Vadoud-Seyedi *et al.* also cite this technique has been used for palmer hyperhidrosis to reduce pain (first paragraph). Furthermore, Vadoud-Seyedi *et al.* indicate the pain injection with a Dermojet is acceptable, and there were neither paresthesias nor other side effects, thus the injection of botulinum toxin with a Dermojet is an effective and comfortable technique (page

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179, third and last paragraph), which is the motivation for a person of ordinary skill in the art to combine the two references to inject a botulinum toxin with a needleless syringe for treating wrinkles and brow furrows, which results in the claimed invention.

Conclusion

9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

May 19, 2004


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